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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/648,864

08/25/2000

Howard M Johnson

UF-243X

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03/25/2004

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/648,864 | Applicant(s) JOHNSON ET AL. | |
| | Examiner Janet L. Andres | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 30-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 30-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 12 January 2004 is acknowledged. Claims 25 and 30-55 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Maintained

2. The rejection of claims 25 and 33-39 under 35 U.S.C. 102(a) and 102(e) as being anticipated by the '816 patent is maintained for reasons of record in the office action of 19 May 2003 and applied to new claims 40-42 and 46-53. The rejection of claims 25, 30-37, and 39 as being anticipated by the '286 patent is maintained for reasons of record in the office action of 19 May 2003 and applied to new claims 40-55.

Applicant argues that a new use for a known composition is patentable subject matter and points to minoxidil, a hypertensive agent now used to promote hair growth. Applicant further argues that an inherent property must be grounded in more than speculation and that a person of ordinary skill in the art must recognize its presence. Applicant argues that it would have been impossible to predict that interferon γ would suppress IgE-type allergies.

Applicant's arguments have been fully considered but have not been found to be persuasive. Minoxidil, prior to the recognition of its hair-growth promoting properties, had been administered orally to treat hypertension. The patents to which Applicant points are for methods of topical administration. Thus the methods are materially different from what was known in the art and would not, based on the known anti-hypertensive properties of minoxidil, have been obvious. That is, until the effect of minoxidil on hair growth was recognized, there was no motivation to administer it topically. In the instant case, however, the method of administration

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is the same as what is known in the art. What is novel is a previously unknown outcome of a known method. That outcome does not render the method itself novel. Furthermore, the patient population to whom the treatment would be administered in view of the newly discovered effect is not separate from the population treated by the methods of the '816 and '286 patents. Suffers from autoimmune disease and suffers from immune system disorders, including allergy, would include a population suffering from IgE-related allergy and such allergies would inherently have been treated by the methods of the '816 and '216 patents, regardless of whether the effect was recognized at the time. It is not, as Applicant states, necessary for that property to have been recognized at the time. What was at issue in *Scaltech* was whether the property actually existed, not whether it was recognized:

If the process that was offered for sale inherently possessed each of the claim limitations, then the process was on sale, whether or not the seller recognized that his process possessed the claimed characteristics...

[W]e vacate the district court's holding and remand for a determination as to whether the process on sale inherently satisfies each claim limitation.

In the instant application, inherency is established by Applicant's own disclosure. According to Applicant's teachings, beneficial effects on IgE-mediated allergy result from the administration of interferon γ . The Examiner does not question these results. However, there is nothing in Applicant's methods that differentiates them from what is taught by the prior art, and the patient populations of the prior art would include sufferers from IgE-mediated allergy. Thus they would have inherently been treated for this condition regardless of whether that fact was recognized at the time.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Janet L. Andres, Ph.D
19 March 2004


JANET ANDRES
PATENT EXAMINER